JUN - 2 2000

K001435

Appendix A

510(k) Summary

Submitter	Guidant Corporation Advanced Cardiovascular Systems, Inc. 26531 Ynez Road, Temecula CA 92591 Contact: Stacey Simon Phone: (909) 914-4527, Fax: (909) 914-2164
Date	May 5, 2000
Device name	Device Trade Name: VIKING OPTIMA™ Guiding Catheter Device Common Name: Percutaneous Catheter Device Classification Name: Guiding Catheter Device Classification: Class II Product Code: 74 DQY
Summary of substantial equivalence	The design, materials, method of operation, and intended use features of the VIKING OPTIMA™ Guiding Catheter are substantially equivalent with regard to these features in the predicate device, the ACS VIKING™ Guiding Catheter, K972484.

510(k) Summary, Continued

Device description	The VIKING OPTIMA™ Guiding Catheter has a standard working length of 100 cm and a standard overall length of 107 cm, but can be produced in lengths from 40 to 160 cm depending upon physician preference and patient size. The VIKING OPTIMA™ Guiding Catheter has a radiopaque shaft, which varies in stiffness at the distal end to accommodate customer preference and give optimal support in each tip shape. The stiffness of the shaft is determined by the durometer of the segment of polymer along the axial length. The lower the durometer of polymer (or polymer blend of Nylon 12 and/or Pebax), the more flexible the guiding catheter. The Pebax raw material durometers vary from 25 to 72D. The guiding catheter also has a radiopaque soft tip at the most distal section. The VIKING OPTIMA™ Guiding Catheter is manufactured in varying tip shapes. Each shape is specific for patient anatomy and physician preference, and therefore a wide range of shapes is available with and without sideholes.
Indications	The guiding catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced.
Technological characteristics	The VIKING OPTIMA™ Guiding Catheter incorporates similar design, components, method of operation, and indication of the predicate device, the ACS VIKING™ Guiding Catheter (K972484) with exception of the dimensions, inner liner material, jacket material, luer color, shaft process, reinforcement wire weld process, labeling, packaging, and sterilization method.
Performance data	The substantial equivalence of the VIKING OPTIMA™ Guiding Catheter has been demonstrated through data collected from nonclinical bench tests and analyses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2000

Ms. Stacey Simon
Regulatory Affairs Coordinator
Guidant Corporation
Vascular Intervention Group
P.O. Box 9018
Temecula, CA 92589-9018

Re: K001435
Trade Name: Viking Optima™ Guiding Catheter
Regulatory Class: II (two)
Product Code: DQY
Dated: May 5, 2000
Received: May 8, 2000

Dear Ms. Simon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of device Evaluation
Center for Devices and
Radiological Health

K001435

Appendix B

Indications Statement

510(k) number (if known):	The 510(k) number has not been issued yet.
Device name	VIKING OPTIMA™ Guiding Catheter
Indications	The guiding catheter is designed to provide a pathway through which therapeutic and diagnostic devices are introduced.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

X	Prescription Use (Per 21 CFR 801.109)	OR	____	Over-The-Counter (Optional Format 1-1-96)